

Hybrigenics gets approval and financing for a Phase II clinical trial of oral inecalcitol in chronic lymphocytic leukemia (CLL)

The French drug agency approves a Phase II study of oral inecalcitol in CLL, an orphan disease characterized by the cancerous proliferation of white blood cells

Hybrigenics raised EUR 1.85 million in a private placement to institutional investors to finance this CLL study

Paris, March 13, 2012 - Hybrigenics SA (ALHYG), a bio-pharmaceutical company listed on Alternext (NYSE-Euronext) in Paris, with a focus on research and development of new treatments against proliferative diseases announces today that the French National Drug Safety Agency has granted authorization for a Phase II clinical trial of oral inecalcitol in patients with chronic lymphocytic leukemia (CLL) under an Investigational Medicinal Product Dossier (IMPD) procedure. Hybrigenics also announces the successful closing of a EUR 1.85 million private placement to institutional investors to finance this new study.

Filed in January this year, Hybrigenics' IMPD application has been approved within the minimum 2-month regulatory timeframe. The open-label clinical study will enrol 50 CLL patients across 6 centres in France and be coordinated by Prof. Hermine, Head of Clinical Haematology at Necker Hospital in Paris, with the endorsement and active participation of the French Cooperative Group on CLL. Patients will receive oral inecalcitol for at least 6 months and/or until progression of the disease. World-wide, about 130,000 new patients are diagnosed each year with CLL, for which a real cure does not exist. CLL is designated as an orphan disease both in the United States, Europe and Japan.

Oral inecalcitol is currently being tested at 4 mg per day for treatment of moderate-to-severe psoriasis in a placebo-controlled double-blind clinical trial. The results of this Phase II study are expected in June 2012. Oral inecalcitol has previously shown excellent tolerance and a strong presumption of efficacy in a phase IIa dose-finding clinical study in prostate cancer in combination with Taxotere®.

A total of 1,650,000 new shares have been issued in a private placement at the price of EUR 1.12 each to several qualified investors based upon the delegation of powers approved by the 12th resolution of the Shareholder's Meeting held on June 25, 2010 and following an accelerated book building procedure according to paragraph II of article L.411-2 of the French Financial and Monetary Code. Bryan Garnier & Co was the exclusive placement agent and book runner.

The new shares represent 11.5% of Hybrigenics' capital before the transaction and 10.3% after. Their price represents a discount of 19% on the mean of the volume-weighted average prices of the last five trading days prior to the closing of the transaction. The proceeds of this placement will be used to manufacture new batches of inecalcitol and of inecalcitol tablets, and to cover the clinical costs of the CLL study.

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"With the rapid authorization of the clinical study by the French drug agency and the accelerated fund-raising focused on its financing, Hybrigenics is all set to test oral inecalcitol in a third potential therapeutic indication: CLL, a cancerous proliferation of white blood cells officially designated as an orphan disease," said Rémi Delansorne, Hybrigenics' CEO.

About Chronic Lymphocytic Leukemia (CLL)

CLL is the most frequent form of leukemia (cancerous proliferative disease of circulating blood cells) and accounts for about 35% of all leukemic patients. Annual estimates of newly diagnosed CLL cases amount to close to 15,000 in the United States (American Leukemia Lymphoma Society, Facts 2012), 14,000 in Europe and 130,000 world-wide (Globocan 2008). CLL is designated as an orphan disease in the United States, Europe and Japan.

People with CLL make too many lymphocytes (mononuclear white blood cells) of one single abnormal "family" (monoclonal) which are not fully developed (immature). Over time, these circulating CLL cells (monoclonal immature lymphocytes) in excess build up in the lymphatic system and cause large, swollen lymph nodes. They may also fill the bone marrow, reducing the number of normal white cells, red cells and platelets that can be made, thereby lowering their blood counts. CLL cannot usually be cured.

About inecalcitol

Inecalcitol is an anti-proliferative vitamin D receptor agonist with a non-calcemic activity by oral administration at doses up to 4 milligrams per day, as observed in a completed Phase IIa clinical study in first-line metastatic castrate-resistant prostate cancer patients, in combination with Taxotere[®]. In addition to the excellent tolerance of inecalcitol, this study also showed a strong presumption of efficacy in 85 % of the treated patients.

The anti-proliferative effectiveness of oral inecalcitol is further being explored in a phase II study in patients with moderate-to-severe psoriasis. All patients have been enrolled in the study and first results are expected in June, 2012.

About Hybrigenics

Hybrigenics (www.hybrigenics.com) is a bio-pharmaceutical company listed (ALHYG) on Alternext (NYSE-Euronext) in Paris, focusing its internal R&D programs on innovative targets and therapies for the treatment of proliferative cancerous or non-cancerous diseases.

Hybrigenics' current development program is based on inecalcitol, a vitamin D receptor agonist, for the first-line treatment of metastatic castrate-resistant prostate cancer in combination with Taxotere[®], which is the current gold-standard chemotherapeutic treatment for this indication. Inecalcitol is also being developed to treat moderate-to-severe psoriasis by oral administration.

Hybrigenics has a research collaboration with Servier on deubiquitinating enzymes and their inhibitors in oncology, neurology, psychiatry, rheumatology, ophthalmology, diabetes and cardiovascular diseases. Hybrigenics continues to build on its pioneer research position in the field of ubiquitin-specific proteases by exploring their role in other areas of particular relevance, such as inflammation and virology.

Hybrigenics Services SAS, a fully-owned subsidiary, is the market leader in Yeast Two-Hybrid (Y2H) and related services to identify, validate and inhibit protein interactions for researchers in all areas of life sciences, using its ISO 9001-certified high-throughput Y2H screening platform, its sophisticated bioinformatics tools and extensive database, along with its chemical library and chemical screening platform.

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HYBRIGENICS is listed on the Alternext by NYSE Euronext Paris

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